



## Framingham SNP Health Association Resource (SHARe) Data Use Certification

### Introduction and Statement of Policy

The National Heart, Lung, and Blood Institute (NHLBI) and Recipient Organization (RECIPIENT) hereby enter into this Data Use Certification (DUC) as of the date specified on the NHLBI Data Access Committee (DAC) approval notification.

The NHLBI has supported the collection of data from three generations in the Framingham Heart Study (FHS): the Framingham Original Cohort, the Framingham Offspring Study, and the Framingham Third Generation Study. The Framingham SHARe Project constitutes a unique scientific resource, consisting of extensive phenotypic information and genotypes for three generations of FHS participants. The NHLBI is committed to making the Framingham SHARe database available, on appropriate terms and conditions, to the largest possible number of qualified investigators in a timely manner.

Framingham SHARe data (genotype-phenotype datasets and pre-computed analyses of them) distributed by the National Center for Biotechnology Information of the National Institutes of Health through the dbGaP under this certification process include data elements that might enable identification of individual participants. Because of the extensive phenotype and genotype data included in the Framingham SHARe database, the NHLBI believes that the confidentiality and privacy of FHS participants can best be assured by requiring all who are interested in accessing the data to acknowledge their review of this DUC and agree to adhere to its provisions. Failure to comply with the provisions of this DUC would be considered in the review of all subsequent requests for access to Framingham SHARe DATA and/or other NHLBI resources. Violation of its confidentiality provisions could lead to legal action on the part of FHS participants, their families, or the U.S. Government.

Note: RECIPIENT requests access to Framingham SHARe data for its PI at its sole risk.

### Definitions

For purposes of this agreement

“DATA” is all information included in the Framingham SHARe database.

A Framingham Heart Study Investigator (FHS INVESTIGATOR) is an individual who

- is employed by the NHLBI to work on the FHS,
- has a current and active consulting agreement with the NHLBI, or
- has a current and active employment contract or consulting agreement with a contractor to the NHLBI to work on the FHS.

REQUESTOR is any organization that is seeking access to DATA, and may be a Public/State Controlled Institution of Higher Education; Private Institution of Higher Education; Nonprofit organization with 501(c)(3) IRS Status (Other than Institution of Higher Education); Nonprofit Organization without 501(c)(3) IRS Status (Other than Institution of Higher Education); Small Business; For-Profit Organization (Other than Small Business); State Government; Government of a U.S. Territory or Possession; Non-domestic (non-U.S.) Entity (Foreign Organization); or Eligible Agency of the U.S. Government.

Principal Investigator (PI) is an individual employed by REQUESTOR who will lead the scientific investigation proposed in the application, oversee the supporting staff who are provided access to the data and contribute to the analytic effort and public disclosure of study results, and assume responsibility for all team members' compliance with the terms and conditions of this DUC.

APPROVED USERS are all individuals specifically identified in the RESEARCH & RELATED Senior/Key Person Profile in the Data Access Request (DAR) that has been approved by the NHLBI DAC. Only the individuals listed in the DAR under the RESEARCH & RELATED Senior/Key Person Profile section are considered APPROVED USER and may have access to the data.

Authorized Institutional Business/Signing Official is an individual with the authority to enter into business transactions on behalf of REQUESTOR.

## Terms of Access

### **1. Research Use**

The REQUESTOR and APPROVED USERS agree that they shall use the Framingham SHARe solely in connection with the research project described in the Data Access Request, which includes the project title, the REQUESTOR's name and the names of all APPROVED USERS, the names of any independent collaborators and their institutions, a 1-2 paragraph description of the research objectives and design, a data security plan, and a brief analysis plan (Research Plan Attachment). New uses of these data outside those described above will require submission of a new application; substantive modifications to the research project will require submission of an amendment to this application. The REQUESTOR and APPROVED USERS further agree that they shall use the Framingham SHARe only in accordance with the parameters described on the Framingham SHARe website for appropriate research uses, and any limitations on such use, of this dataset.

**DATA USE LIMITATIONS FOR FRAMINGHAM SHARE: Framingham SHARe may not be used to investigate individual pedigree structures, individual participant genotypes, or issues such as non-paternity.**

The REQUESTOR and APPROVED USERS further acknowledge that they are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and any relevant institutional policies, and that the data are always maintained in a secured fashion.

It is anticipated that, at least in some cases, the Framingham SHARe will be updated with additional information and will be so identified by an appropriate version number. Unless

otherwise indicated, all statements herein are presumed to be true and applicable to the access and use of all versions of the Framingham SHARe.

REQUESTOR and APPROVED USERS acknowledge that other researchers have access to Framingham SHARe so that duplication of research is possible.

This Data Use Certification is good for three (3) years from the date of approval for access. However, access to the data from beyond the first and second year anniversaries is subject to receiving the annual report. No further research can be done using these DATA until a new Data Access Request is approved.

## ***2. Institutional and Approved User Responsibilities***

The REQUESTOR and APPROVED USERS agrees through the submission of the Data Access Request that he or she has reviewed and understands the principles for responsible research use and data handling of the genotype and phenotype data included within NIH GWAS datasets as defined in the NIH GWAS Data Sharing Policy (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>) and detailed in this Data Use Certification agreement. The Requester and his or her institution further acknowledge that they are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and regulations and any relevant institutional policies. Through submission of the DAR, the REQUESTOR and APPROVED USERS also agrees to submit annual reports to the appropriate NIH Data Access Committee (DAC) describing his or her research use as an Approved User of the Framingham SHARe dataset as described under “Research Use Reporting” below.

REQUESTOR and APPROVED USERS who may have access to personal identifying information for research participants in the original study, at their institution or through their collaborators, may be required to have IRB approval for their research protocol. By approving and submitting the attached Data Access Request, the Institutional Signing Official provides assurance that relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including IRB approval if required. The Institutional Signing Official also assures through the approval of the Data Access Request that other organizations within the institution with relevant authorities (e.g., the Office of Technology Transfer, the Chief Information Officer, the Office of Human Subjects Research, etc.) have reviewed the relevant sections of the NIH GWAS Data Sharing Policy and the associated procedures and are in agreement with the principles defined.

It is anticipated that, at least in some cases, these datasets will be updated with additional information. Unless otherwise indicated, all statements herein are presumed to be true and applicable to the access and use of all versions of these datasets.

## ***3. Public Posting of Approved User’s Research Use Statement***

The Requester agrees that, if he or she becomes an Approved User, information about the proposed research use can be posted on a public web site that describes the projects. The information may include the Approved User’s name and institution, project name, Research Use Statement, and a Non-technical Summary of the Research Use Statement. In addition, citations resulting from the use of NIH GWAS datasets will be posted on the NIH GWAS Data Repository website.

#### **4. Non-Identification**

APPROVED USERS agree not to use NIH GWAS datasets, either alone or in concert with any other information, to identify or contact individual participants from whom phenotype data and DNA samples were collected. This agreement does not apply to research investigators operating with specific IRB approval to contact individuals within datasets under an approved IRB research protocol.

#### **5. Non-Transferability**

The APPROVED USERS agree to retain control over the DATA, and further agree not to distribute the individual data in any form to any entity or individual other than their research staff or trainees or independent collaborating investigators listed in the Framingham SHARe Data Access Request under "RESEARCH & RELATED Senior/Key Person Profile" who also agree to the terms within this Data Use Certification, subject to applicable law. The REQUESTOR and APPROVED USERS agree to store the Framingham SHARe on a computer with adequate security controls, and to maintain appropriate control over the data at all times. If APPROVED USERS are provided access to NIH GWAS datasets for inter-institutional collaborative research described in the research use statement of the Data Access Request, and all members of the collaboration are also APPROVED USERS, derivatives of the dataset may be securely transmitted within the collaborative group for the purpose of quality control or other research requirements. All data security practices and other terms of use defined in this agreement and the dbGaP Security Best Practices (<http://www.ncbi.nlm.nih.gov/projects/gap/pdf/dbGaPLevel2SecurityProcedures.pdf>) for the original data are expected to be followed for the derived data, including any transmission of the data.

The REQUESTOR and APPROVED USERS acknowledge responsibility for ensuring the review and agreement to the terms within this Data Use Certification and the appropriate research use of NIH GWAS data by research staff associated with any approved GWAS Project, subject to applicable laws and regulations. NIH GWAS Datasets containing individual-level information, in whole or in part, may not be sold to any individual at any point in time for any purpose.

The APPROVED USER agrees that if he or she changes institutions during the period of the DAR approval, a new Data Access Request and Data Use Certification from the new institution will be submitted and approved before data use resumes. Any versions of data stored at the prior institution will be destroyed and documented through a final Data Use Report as described below. However, if advance written notice and approval by the NHLBI Data Access Committee is obtained to transfer responsibility for the approved research project to another Approved User within the same institution; the data may not need to be destroyed.

#### **6. Data Security and Data Release Reporting**

The Requester and his/her institution acknowledge that they, the Information Technology Director or his/her designee, and all other individuals named in the Data Access Request have reviewed and agree to handle the Framingham SHARe dataset(s) according to the current dbGaP Security Best Practices (<http://www.ncbi.nlm.nih.gov/projects/gap/pdf/dbGaPLevel2SecurityProcedures.pdf>), including

its detailed description of requirements for security and encryption. This includes, but is not limited to:

- all approved users have completed all required institutional computer security training, e.g. <http://irtsectraining.nih.gov/>, or the equivalent;
- the data will always be physically secured (e.g. through camera surveillance, locks on doors/computers, security guard);
- servers must not be accessible directly from the internet, (i.e. must be behind a firewall or not connected to a larger network) and unnecessary services disabled;
- use of portable media, e.g., on a CD, flash drive or laptop, is discouraged, if necessary then they must be encrypted;
- updated anti-virus/anti-spyware software;
- security auditing/intrusion detection software, detection and regular scans of potential data intrusions;
- strong password for file access and never share it.
- All copies of the dataset must be destroyed whenever any of the following occurs:
  - the DUC expires
  - the [I/C] requests destruction of the dataset
  - the continued use of the data would no longer be consistent with the DUC.
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In addition, APPROVED USER agrees, along with the institution, to keep the data secure and confidential at all times and to adhere to information technology practices in all aspects of data management to ensure that only authorized individuals can gain access to NIH GWAS datasets. This agreement includes the maintenance of appropriate controls over any copies of the data.

Approved Users and his/her institution agree to notify the NHLBI Data Access Committee of any unauthorized data sharing, breaches of data security, or inadvertent data releases that may compromise data confidentiality within 24 hours of when the incident is identified. Notifications should include the known information regarding the incident and a general description of the activities or process in place to fully define and remediate the situation. Within 3 business days of the NIH notification, the Institution, through the Approved User and the Institutional Signing Official, agree to submit to the NHLBI DAC a more detailed written report including the date and nature of the event, actions taken or to be taken to remediate the issue(s), and plans or processes developed to prevent further problems, including specific information on timelines anticipated for action.

**All notifications and written reports of data security incidents should be sent to:**

NHLBI Data Access Committee Chair

Email: [nhlbigeneticdata@mail.nih.gov](mailto:nhlbigeneticdata@mail.nih.gov)

FAX: 301-480-7971

The NHLBI, the NIH, or another entity designated by the NIH may also investigate any data security incident. Approved Users and their associates agree to support such investigations and provide information, within the limits of applicable local, state and federal laws and regulations. In addition, APPROVED USERS and his/her institution agree to work with the NHLBI and the NIH to assure that plans and procedures developed to address identified problems are mutually acceptable.

## **7. Intellectual Property**

By requesting access to the Framingham SHARe dataset(s), the REQUESTER and APPROVED USER acknowledge the intent of the NIH to see that Approved Users, and anyone else authorized for research access through the Data Access Request, follow the intellectual property principles within the NIH GWAS Policy for Data Sharing (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>) as summarized below:

Achieving maximum public benefit is the ultimate goal of data distribution through the NIH GWAS Data Repository. The NIH believes that these data should be considered as pre-competitive, and urges Approved Users to avoid making IP claims derived directly from the GWAS dataset(s). However, the NIH also recognizes the importance of the subsequent development of IP on downstream discoveries, especially in therapeutics, which will be necessary to support full investment in products to benefit the public.

It is expected that these NIH-provided data, and conclusions derived therefrom, will remain freely available, without requirement for licensing. The NIH encourages broad use of GWAS datasets coupled with a responsible approach to management of intellectual property derived from downstream discoveries in a manner consistent with the NIH's Best Practices for the Licensing of Genomic Inventions ([http://www.ott.nih.gov/policy/genomic\\_invention.html](http://www.ott.nih.gov/policy/genomic_invention.html)) and the NIH Research Tools Policy ([http://grants.nih.gov/grants/intell-property\\_64FR72090.pdf](http://grants.nih.gov/grants/intell-property_64FR72090.pdf)).

## **8. Research Dissemination and Acknowledgement of NIH GWAS Datasets**

It is the intent of the NIH to promote the dissemination of research findings from NIH GWAS dataset(s) as widely as possible through scientific publication or other appropriate public dissemination mechanisms. Approved Users are strongly encouraged to publish their results in peer-reviewed journals and to present research findings at scientific meetings, etc. In accord with the NIH GWAS Policy for Data Sharing (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html#publication>), and as expressed through the Requester's submission of the DAR, Approved Users agree not to submit findings using the Framingham SHARe dataset(s), or updated versions thereof, for publication or presentation for a period of exclusivity for Contributing Investigators concluding with the Embargo Date identified on the NIH GWAS Data Repository.

The Requester agrees to acknowledge the NIH GWAS Data Repository, the Contributing Investigator(s) who contributed the phenotype data and DNA samples from his/her original study, and the primary funding organization that supported the contributing study in all oral and written presentations, disclosures, and publications resulting from any analyses of the data. The Requester further agrees that the acknowledgment shall include the dbGaP accession number to the specific version of the dataset(s) analyzed.

A sample statement to be used in acknowledgments is:

"The Framingham Heart Study and the Framingham SHARe project are conducted and supported by the National Heart, Lung, and Blood Institute (NHLBI) in collaboration with Boston University. The Framingham SHARe data used for the analyses described in this manuscript were obtained through dbGaP (accession numbers). This manuscript was not prepared in collaboration with investigators of the Framingham Heart Study and does not necessarily reflect the opinions or views of the Framingham Heart Study, Boston University, or the NHLBI."



## **9. Research Use Reporting**

To ensure that NIH policies and procedures for participant protection and other elements of GWAS data use are adhered to, Approved Users agree to provide annual feedback on how these data have been used and any results that have been generated as a result of access to the data, including patents and publications. This information will be used by the NHLBI DAC staff as required for program oversight activities and by the NIH GWAS Governance committees as part of the NIH effort to provide ongoing oversight and management of all NIH GWAS activities.

APPROVED USERS thus agree to provide a brief annual report summarizing the progress of the research specified within this Data Use Certification for the period of time that the Data Use Certification is in effect (three (3) years from approval date). Those not seeking renewal will be asked to provide specific information to the Data Access Committee via the contact information below. Annual Data Use Reports will provide information regarding potentially significant findings and publications or presentations that resulted from the use of the Framingham SHARe dataset(s), a summary of any plans for future research use, any violations of the terms of access described within this Data Use Certification and the implemented remediation, and information on any downstream intellectual property generated as a result of the data. Approved Users also may be asked to provide general comments regarding topics such as the effectiveness of the NIH GWAS data access process, such as ease of access and use, appropriateness of data format, challenges in following the policies, and suggestions for improving data access or the program in general.

Annual reports for Years 1 and 2 of this Certification should be submitted on the first day of the month following the anniversary date of this Certification (as indicated by the date the data were made accessible to the APPROVED USER). The Year 3 annual report should be submitted as an attachment to any renewal Data Use Certification submitted, or by the last day of the month following the anniversary date of this Certification.

### **Annual Data Use Reports should be submitted to:**

NHLBI Data Access Committee Chair  
Email: [nhlbigeneticdata@mail.nih.gov](mailto:nhlbigeneticdata@mail.nih.gov)  
FAX: 301-480-1455

**Note that any inadvertent or inappropriate data release incidents should be reported to the NHLBI DAC according to the agreements and instructions under Term 6.**

## **10. Non-Endorsement, Indemnification**

The Requester and his/her institution acknowledge that although all reasonable efforts have been taken to ensure the accuracy and reliability of NIH GWAS data, the NIH, the NHLBI, and Contributing Investigators do not and cannot warrant the results that may be obtained by using any data included therein. The NIH, the NHLBI, and all contributors to these datasets disclaim all warranties as to performance or fitness of the data for any particular purpose.

No indemnification for any loss, claim, damage or liability is intended or provided by any party under this agreement. Each party shall be liable for any loss, claim, damage, or liability that said party incurs as a result of its activities under this agreement, except that the NIH, as an agency

of the United States, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. 2671 et seq.

### **11. Termination and Violations**

This Data Use Certification will be in effect for a period of three (3) years from the date the data were made accessible to the Approved User ("Approved Access Date"). At the end of the three (3) year period, the Approved User agrees to destroy all copies of the NIH GWAS dataset(s), and all derivatives that contain individual-level information.

Consideration will be given to a renewal of this agreement upon submission of a new DAR. Copies of NIH GWAS dataset(s) may not need to be destroyed if, with advance notice and approval by the NHLBI Data Access Committee, documentation is provided that other Approved Users at the same institution are using the dataset(s) under an active DAC approved research project.

The NIH or the NHLBI may terminate this agreement and immediately revoke access to all NIH GWAS datasets at any time if the Requester is found to be no longer in agreement with the policies, principles and procedures of the NIH and the NHLBI.

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By submission of the Framingham SHARe Data Access Request, the REQUESTOR and APPROVED USERS attest to the APPROVED USERS qualifications for access to and use of Framingham SHARe DATA and certify their agreement to the NIH GWAS principles, policies, and procedures for the use of Framingham SHARe DATA as articulated in this document.

APPROVED USERS further acknowledge that they have shared this document and the NIH GWAS policies and procedures for access and use of GWAS datasets with any research staff who will participate in the use of the Framingham SHARe DATA.

Institutional Signing Officials acknowledge that they have considered the relevant NIH GWAS policies and procedures, that they have shared this document and the relevant policies and procedures with appropriate institutional organizations, and have assured compliance with local institutional policies related to technology transfer, information technology, privacy, and human subjects research.

With the submission of this application the Signing Official/REQUESTOR affirms that the Organization IT Director for REQUESTOR and APPROVED USERS understand that it is their responsibility to protect the confidentiality of the participants in the Framingham Heart Study. Furthermore, the Signing Official / REQUESTOR affirms that the Organization IT Director and all APPROVED USERS listed in the Data Access Request under the RESEARCH & RELATED Senior/Key Person Profile section have read the Data Use Certification and the data security policy and agree to observe and enforce them in all aspects of work on this project. Only the individuals listed in the RESEARCH & RELATED Senior/Key Person Profile section will be considered APPROVED USERS and will have access to the data.